K011251 (1 of 2)

AUG 1 2001

510(k) Summary
SPARC™ Sling System
510(k) Number _____

Submitter/Contact Person:

Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

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Device Name and Classification:

Trade Name: SPARC™ Sling System
Common/Usual Name: Surgical Mesh, Sling, Urethral Sling
Classification Name: Surgical Mesh, polymeric
Product Code: FTL
Classification: Class II

Manufacturing Location:

American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:

Tension Free Vaginal Tape (TVT) System by Ethicon, Inc. - K974098

Indications for Use:

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Description:

The SPARC™ Sling System is a sterile, single use procedure kit consisting of:

- Two stainless steel, curved, 22-cm long, needle passers (also called insertion tools).
- One piece of AMS Polypropylene sling mesh with attached dilating connectors. The AMS Polypropylene sling mesh is constructed of polypropylene monofilament that is precut to 1.0cm

width x 50cm length. A fixed blue polypropylene anchoring suture runs through the middle of the sling mesh. Two plastic sheaths that overlap in the center of the sling mesh, cover the sling mesh and protect it during placement.

Dilating connectors are attached to either end of the plastic sheaths. The dilating connectors are used to attach to the vaginal ends of the SPARC™ needle passers during the procedure to facilitate sling placement.

- Two blue colored plastic cystoscopy aids are included in the kit in order to facilitate cystoscopic viewing of the bladder. The use of these cystoscopy aids is optional.

Summary of Testing

The material used in the SPARC™ Sling System has been demonstrated to be biocompatible.

The SPARC™ Sling System has been tested for a variety of physical characteristics including tensile strength and suture pull strength and has been shown to be equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Ginger Sackett Glaser
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K011251
Trade/Device Name: SPARC™ Sling System
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTL
Dated: June 12, 2001
Received: June 13, 2001

Dear Ms. Glasser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011251

Device Name: SPARC™ Sling System

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011251

(Optional Format 3-10-98)